In re Appln. of PARIKH et al. Application No. 09/443,863

IN THE CLAIMS:

Replace the indicated claims with:

(Amended) A process for the preparation of a rapidly disintegrating solid dosage form capable of forming a stable suspension without irreversible particle aggregation and/or particle agglomeration or particle growth comprising:

- a) forming an admixture of a stable aqueous homogenous suspension of micronized surface stabilized primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents, wherein said stable aqueous primary particle suspension has a particle size of about $10 \mu m$ or less, each primary particle is a solid drug particle on to which is adsorbed at least one surface modifying agent of which one is a phospholipid, ;
- b) drying said admixture to produce a solidified suspension of said surface stabilized primary particles dispersed and embedded throughout a support matrix of said matrix-forming agent or agents, wherein said matrix dissolves or substantially disperses in a rapid disintegration time when in contact with an aqueous environment to release said surface stabilized primary particles into said aqueous environment as a suspension without irreversible particle aggregation and/or particle agglomeration and without particle size growth;
- c) optionally course milling and blending said solidified suspension with one or more pharmaceutically acceptable excipients to provide a dried powder; and
 - d) forming said dried material or said dried powder into a solid dosage form.

(Amended) A process for the preparation of a rapidly disintegrating solid dosage form capable of forming a stable suspension without irreversible particle aggregation and/or particle agglomeration or particle growth comprising:

- a) forming an admixture of a stable aqueous homogenous suspension of micronized surface stabilized primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents, wherein said stable aqueous primary particle suspension has a particle size of about 10 µm or less, each primary particle is a solid drug particle on to which is adsorbed at least one surface modifying agent of which one is a phospholipid;
 - b) distributing the admixture of (a) into unit dosage form molds; and
- c) freeze-drying said admixture in said unit dosage form molds to produce a solidified suspension of said surface stabilized primary particles dispersed and embedded throughout a

7

74



In re Appln. of PARIKH et al. Application No. 09/443,863

Corell.

support matrix of said matrix-forming agent or agents, wherein said matrix dissolves or substantially disperses in a rapid disintegration time when in contact with an aqueous environment to release said surface stabilized primary particles into said aqueous environment as a suspension without irreversible particle aggregation and/or particle agglomeration and without particle size growth.

Add the following claim:

45

Mew) A rapidly dispersing solid therapeutic dosage form capable of forming a stable suspension without irreversible particle aggregation and/or particle agglomeration or particle growth comprising particles of a water-insoluble compound, the water-insoluble particles being surface stabilized with one or more surface modifiers of which at least one is a phospholipid and having a particle size of about 10 μm or less, the surface-stabilized particles dispersed throughout a bulking matrix optionally also including a releasing agent, wherein when the solid therapeutic dosage form is introduced into an aqueous environment, the bulking/releasing matrix is substantially completely disintegrated and the surface stabilized water insoluble particles are released in an unaggregated and/or unagglomerated state to form a stable aqueous suspension.

